

Docket No.: 2003.810US  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Jaap Van Der Louw et al.

Confirmation No. 8561

Application No.: 10/584,006

Filed: June 22, 2006

Art Unit: 4161

For: STEROIDS HAVING A MIXED  
ANDROGENIC AND PROGESTAGENIC  
PROFILE

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Examiner: Paul E. Zarek

**RESPONSE TO RESTRICTION REQUIREMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Office Action dated September 9, 2008.

The Commissioner is authorized to charge any deficiency to Deposit Account No. 50-4205.

The Examiner has indicated that the claimed subject matter is drawn to three distinct inventions and has required restriction to one of the following inventions:

- |           |   |
|-----------|---|
| Group I   | Claims 1-4, 6, 8 and 10-14 drawn to a compound of formula I or composition thereof;                             |
| Group II  | Claim 15, drawn to a method of male contraception comprising administration of formula I;                       |
| Group III | Claim 16, drawn to a method of treating androgen insufficiency in males comprising administration of formula I. |

The Examiner also states *inter alia*:

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1, because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Ananchenko, et al. (Tetrahedron, 1962, provided in IDS), teach an embodiment of formula I wherein R1 is O, R2 is methyl and R3 is H (pg. 1359, compound XXVII). Therefore, the claimed invention lacks a special technical feature.

Applicants hereby provisionally elect with traverse to prosecute the claims of Group I, claims 1-4, 6, 8 and 10-14 drawn to a compound of formula I or composition thereof. With respect to the requirement to elect a single disclosed species, Applicants hereby request examination of the provisionally elected claims electing with traverse the species of (7 $\alpha$ , 17 $\alpha\beta$ )-17 $\alpha$ -hydroxy-7,17 $\alpha$ -dimethyl-D-homoestr-4-en-3-one. The elected species, (7 $\alpha$ , 17 $\alpha\beta$ )-17 $\alpha$ -hydroxy-7,17 $\alpha$ -dimethyl-D-homoestr-4-en-3-one, is readable on claims 1-4 and 6 (R1=O, R3=hydrogen, R2=methyl).

Applicants expressly reserve the right to file a divisional application encompassing the claims of non-elected Groups II and III prior to issuance of this application. In addition, Applicants expressly reserve the right to rejoin the claims of the non-elected groups upon allowance of one or more of the claims of elected Group I. Applicants also retain the right to petition from this requirement under 37 C.F.R. §1.144.

This election is made with traverse because it is submitted that the presently claimed compound of formula I is believed to be unknown in the art. While the Examiner contends that Ananchenko et al. teach an embodiment of the compound of formula I, compound XXVII, it is asserted that compound XXVII is not an embodiment of the compound of formula I, i.e., it does not fall under the scope of the compound of formula I. In this regard, Compound XXVII is not substituted by an alkyl residue at both the 7 and 17 positions, whereas the compound of formula I is substituted by an alkyl residue at both the 7 and 17 positions. Accordingly, it is submitted that the compound of formula I was not known in the art, and that the compound of formula I links Groups I (product), II and III (II and III directed to process of using the product) together as the special technical feature. Accordingly, it is submitted that unity exists between Groups I, II and III.

It is further submitted that since method of use claims of Groups II and III require the same compound of the Formula I as the claims of Group I, that the search of Groups I, II and III would have extensive overlap of art. Accordingly, examination of Groups I, II and III together would not impose a serious burden on the Examiner.

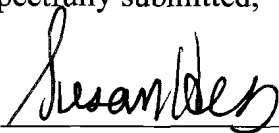
In view of the above, it is believed that Groups I-III should be examined as a single group.

Early and favorable action is respectfully requested.

Dated: October 9, 2008  
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Respectfully submitted,

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